

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

STRYKER CORPORATION, et al.,

Plaintiffs,

File No. 4:01-CV-157

v.

HON. ROBERT HOLMES BELL

XL INSURANCE AMERICA INC., formerly
known as WINTERTHUR INTERNATIONAL
AMERICA INSURANCE COMPANY,

Defendant.

O P I N I O N

Plaintiffs Stryker Corporation ("Stryker") and Howmedica Osteonics Corporation ("HOC") filed this action against Defendant XL Insurance America Inc. ("XLIA") formerly known as Winterthur International America Insurance Company,¹ alleging that XLIA breached the terms of the Commercial Umbrella Policy (the "Policy")² that XLIA wrote for Stryker. Stryker alleges that XLIA breached the Policy when XLIA denied Stryker's claim under the Policy. Plaintiffs seek declaratory relief and damages. The Court bifurcated trial on this matter, with the first phase of the trial being limited to whether there is coverage

¹For simplicity the Court will use XLIA throughout the opinion, including references to the company during the time period when it was known as Winterthur.

²"Policy" as used herein refers to the Commercial Umbrella Policy, inclusive of all endorsements.

under the Policy. This matter was tried to the Court on January 29 - February 2, 2007. The Court heard the live testimony of Edward B. Lipes, Group President of HOC,³ Elizabeth A. Staub, Vice-President of Regulatory, Quality and Clinical at HOC, Michael G. Cartier, Deputy General Counsel at Stryker, Thomas P. Schmalzried, M.D., Stryker's expert witness on orthopedic medicine, Douglas O'Connor, Associate Director of Application Development at HOC, Curtis E. Hall, General Counsel at Stryker, Daniel J. Dean, insurance broker, and Michael Gaines, National Loaner Bank Team Leader at HOC. The Court reviewed the video depositions of Duane Anderson, M.D., orthopedic surgeon, Gordon Blunn, Ph.D., XLIA's expert on orthopedic implants, Bradley Chase, Business Unit Manager for Knees at HOC, Gerard A. Engh, M.D., orthopedic surgeon, John K. Pike, M.D., orthopedic surgeon, Kathleen Puscas, Client Advisor at Marsh, and Geoffrey Welsher, Middle Market Practice Leader at Marsh. The Court also reviewed the deposition transcripts of Jadwiga Degrado, Quality Assurance Representative at HOC, Dyanne Diemer Kashuba, Product Manager for the Duracon Uni-Knee at Howmedica Inc., and Brad Kuchinic, Underwriter at XLIA. This opinion contains the Court's findings of fact and conclusions of law in accordance with Rule 52(a) of the Federal Rules of Civil Procedure.

I.

The Duracon Unicompartmental Knee ("Uni-Knee") was a line of artificial implantable knees manufactured by Howmedica Inc., a subsidiary of Pfizer Inc. From 1997

³These are the titles that were applicable in 1999 and 2000.

until December 4, 1998, Howmedica Inc. sold the Uni-Knees in the United States. On December 4, 1998, Stryker acquired certain assets of Howmedica Inc., including the Uni-Knees remaining in inventory. On December 31, 1998, the two subsidiaries of Stryker that had acquired the assets of Howmedica Inc. were merged into Osteonics Corp., a subsidiary of Stryker Corporation. Osteonics Corp. then changed its name to Howmedica Osteonics Corporation. After the acquisition, the Uni-Knees compromised less than one ten-thousandth of Stryker's total sales. (Lipes Test., Trial Tr. 96:4-13.)

The Uni-Knees were sterilized using gamma irradiation. One consequence of the gamma irradiation was that the Ultrahigh Molecular Weight Polyethylene ("UHMWPE") in the Uni-Knees would oxidize while exposed to air. In January of 1996, based on a body of scientific knowledge that developed in the mid-1990s, Howmedica Inc. established a five-year shelf life policy. (Trial Ex. 7, at 1; Trial Ex. 32, at ¶¶ 17, 18.) Under this policy, no product containing UHMWPE was to be implanted more than five years after being gamma irradiated. (Trial Ex. 7, at 1; Trial Ex. 32, at ¶ 15.) In furtherance of this policy, Howmedica Inc. developed a computerized inventory control system. (O'Connor Test., Trial Tr. 439:17-445:3.) This inventory control system was referred to as the "poly-filter file" or the "poly-filter system." (*Id.* at 446:14-447:1, 458:14-18.)⁴ The poly-filter file was designed to prevent Howmedica Inc. from shipping any products that contained gamma irradiated UHMWPE

⁴The team that developed the poly-filter file was headed by Douglas O'Connor. (O'Connor Test. 438:19-441:2.) Mr. O'Connor testified live at trial and the Court found him to be a credible witness.

more than four years after the product was gamma irradiated. (*Id.* at 447:4-15.) The limitation of four years for shipping from Howmedica Inc. was intended to create a buffer for the five-year shelf life policy. (*Id.* at 447:24-448:14.)

HOC continued with the five-year shelf life policy that had been implemented by Howmedica Inc. (Lipes Test. 83:12-84:3.) After the asset purchase, the newly formed HOC continued to use the poly-filter file that had been developed by Howmedica Inc. The team at Howmedica Inc. who developed and implemented the poly-filter file identified approximately 4,000 products that contained UHMWPE. (O'Connor Test. 439:11-16, 448:19-24, 460:25-461:5.) The Uni-Knees were identified as a product to be entered into the poly-filter file; however, the Uni-Knees were inadvertently not entered into the poly-filter file. (*Id.* at 458:8-13, 461:6-463:22; Trial Ex. 27.) As a result, Uni-Knees with UHMWPE components gamma irradiated in 1993 remained available in inventory in 1998, 1999 and early 2000. Ultimately, some of these Uni-Knees were implanted and the UHMWPE components experienced wear at an abnormally high rate because the implantation took place after the expiration of the five-year shelf life. The abnormally high wear and associated problems resulted in the need for some of the Uni-Knees to be revised and other complications.

Some of the patients who received the expired Uni-Knees brought claims or lawsuits against HOC and Stryker. Stryker sought coverage under the Policy from XLIA. On October 11, 2001, XLIA denied coverage under the Policy. (Trial Ex. 76.)

This case had originally been set for a jury trial and in preparation for the jury trial the Court had prepared a special verdict form that identified the four factual questions to be answered by the jury. (Special Verdict Form, Oct. 14, 2005 R&R, Docket #777, Attach. 2, *approved and adopted by* July 14, 2006 Order, Docket #814.) These four factual questions comprised the matter tried to the Court on January 29 - February 2, 2007.

II.

Under Michigan law, the insured bears the burden of proof on the elements of a *prima facie* case establishing coverage. (Aug. 17, 2005 Op., Docket #689, at 7-8); *Heniser v. Frankenmuth Mut. Ins.*, 449 Mich. 155, 161 n.6, 534 N.W.2d 502 (1995). Questions 1 and 2 on the special verdict form relate to Plaintiffs' *prima facie* case. Therefore, Plaintiffs have the burden of proof on Questions 1 and 2. (July 14, 2006 Op., Docket #813, at 25-28.) The Court must determine the facts under a preponderance of the evidence standard. *Blue Cross & Blue Shield v. Milliken*, 422 Mich. 1, 89, 367 N.W.2d 1 (1985).

A. **Did the parties intend that the Policy would cover all claims and lawsuits involving products in a single batch, no matter when bodily injury took place?**

Stryker and XLIA entered into a contract, the Commercial Umbrella Policy, for commercial umbrella coverage for the year 2000. (Commercial Umbrella Policy ("Policy"), Trial Ex. 1.) Though there were several significant endorsements, this Policy was a standard policy in that it covered the negligent acts of Stryker. The Court previously ruled that the Policy is ambiguous as to whether there is coverage for claims and lawsuits involving products in a single batch regardless of when bodily injury took place. (July 14, 2006 Op.

2-5; Aug. 17, 2005 Op. 10-12.) The meaning of an ambiguous provision of a contract is a question of fact to be decided by the trier of fact. *See Klapp v. United Ins. Group Agency Inc.*, 468 Mich. 459, 469, 663 N.W.2d 447 (2003).

The Policy provides that XLIA:

will pay on behalf of the Insured those sums in excess of the Retained Limit that the Insured becomes legally obligated to pay by reason of liability imposed by law or assumed by the Insured under an insured Contract because of Bodily Injury . . . that takes place during the Policy Period and is caused by an Occurrence happening anywhere in the world.

(Policy ¶ I.) There are several endorsements to the Policy, however, only two are relevant to this case. Endorsement No. 17 replaces paragraph 3 in Endorsement No. 15 with the following language:

As used in this endorsement, the term "batch" shall mean all medical products which have the same known or suspected defect or deficiency which is identified by the same advisory memorandum. The date of the advisory memorandum will be considered the date of occurrence for all claims resulting from or relating to the batch. Any advisory memorandum shall not change a date of occurrence that has already been established. For an individual explant of [*sic*] claim to be considered part of a batch, the date of occurrence, as defined in Paragraph 1, above, must be subsequent to 1-1-00. Batch coverage shall not apply to any loss, which arises out of a defect, or deficiency that is known or suspected prior to 1-1-00.

(Policy, Endorsement No. 17.) The Court will refer to Endorsement No. 15, as modified by Endorsement No. 17, as the Medical Products Endorsement. The Court previously determined on summary judgment that there was an "occurrence" within the meaning of the Medical Products Endorsement. (July 14, 2006 Op. 7-9.)

Plaintiffs contend that by adopting the Medical Products Endorsement, the parties intended that lawsuits or claims involving a batch of implantable medical products would be included in a single policy year, regardless of when bodily injury took place. Defendant contends that each claim and lawsuit against the insured is only covered if the insured can prove bodily injury occurred between January 1, 2000, and January 1, 2001.

The strongest support in the text of the Policy for Plaintiffs' interpretation is the second sentence of Endorsement No. 17: "The date of the advisory memorandum will be considered the date of occurrence for all claims resulting from or relating to the batch." (Policy, Endorsement No. 17.) The intent of the parties to have the second sentence bring claims and lawsuits from outside of the policy period into the batch is also evidenced by the fourth sentence. The fourth sentence excludes claims or lawsuits that have a "date of occurrence" prior January 1, 2000, using the "date of occurrence" definition in paragraph one. (*Id.*) The definition of "date of occurrence" in paragraph one provides for reference to: the date of explant, the date a claim or lawsuit is brought, the date a professional opinion is rendered, or the date of death. (Policy, Endorsement No. 15, ¶ 1.) If language in the second sentence was not intended to include claims outside of the policy period in a given batch, then the fourth sentence is surplusage. This is not the only reasonable reading of the Policy, so the Court must consider extrinsic evidence.

The broker for the policy was Marsh Inc. (Welsher Dep. 594:20-595:19.) The underwriter for the policy at XLIA was Brad Kuchinic. (Kuchinic Dep. 7:3-9, 49:15-17.)

XLIA sought the inclusion of the Medical Products Endorsement because of Stryker's medical products business. (*Id.* at 75:13-76:10, 82:18-83:10.) Curtis Hall, General Counsel at Stryker, testified live at trial as to his involvement in the negotiations of the Policy and particularly the Medical Products Endorsement. The Court found Mr. Hall to be a credible witness. The addition of the Medical Products Endorsement altered Stryker's coverage, which caused Stryker to question the effect of the Endorsement. (Hall Test., Trial Tr. 482:14-483:11.) Mr. Hall testified that his understanding at the time was that the Endorsement brought all claims that were part of the same batch into a single policy year. (*Id.* at 483:12-484:10.) Mr. Hall assigned one of his attorneys, Michael Cartier, to assist the risk management group at Stryker to evaluate the policy. (*Id.* at 484:11-18.)

Mr. Cartier testified live at trial and the Court found him to be a credible witness. In early December of 1999, Mr. Cartier participated in a series of conference calls with Daniel J. Dean, of Marsh Inc. (Cartier Test., Trial Tr. 327:23-328:16, 329:1-330:11.) At trial Mr. Dean testified as to what he explained about the Medical Products Endorsement during those conference calls. The Court found Mr. Dean to be a credible witness.

The conference calls with Mr. Dean came about because he had originally drafted an almost identical endorsement while employed by Intermedics Inc. (Dean Test., Trial Tr. 532:11-540:18; Cartier Test. 329:9-11.) While at Intermedics Mr. Dean, in conjunction with Intermedics' insurer, Travelers, drafted an endorsement for medical products that was incorporated into Intermedics' insurance policy with Travelers. (Dean Test. 534:11-536:13,

537:4-543:12, 549:18-550:4.) During the conference calls with Stryker, Mr. Dean explained his understanding of the Medical Products Endorsement. (Dean Test. 543:13-550:4; Cartier Test. 329:12-20.) Mr. Dean explained that the Medical Products Endorsement brought all of the claims for a single batch into one policy year. (Dean Test. 543:13-547:19; Cartier Test. 329:12-20.) The date of occurrence and the composition of the batch would be defined by the "advisory memorandum" or the "Dear Doctor" letter. (Dean Test. 546:9-547:19.) Mr. Dean also explained that in the event of a product recall, or similar type of event, the language in the Medical Products Endorsement provides the following benefits. The insured benefits because it will only need to exhaust one self-insured retention limit. (*Id.* at 540:25-541:10, 544:17-546:8.) Otherwise, the insured would need to exhaust the self-insured retention limit in each new policy year. The insurer benefits because the insured will not be able to "stack" multiple policy limits. (*Id.* at 539:23-540:11, 544:23-545:7.) "Stacking" in this context means bringing claims in multiple policy years for claims that are part of the same recall. (*Id.* at 540:2-11.)

After his tenure with Intermedics, Mr. Dean was employed as an insurance broker. (*Id.* at 553:20-554:3.) Mr. Dean eventually became the insurance broker for Intermedics' successor, SulzerMedica. (*Id.* at 554:23-555:16.) After 1990, XLIA provided SulzerMedica's general liability coverage. (*Id.* at 555:8-21.) XLIA's general liability coverage for SulzerMedica adopted almost verbatim the batch coverage provision that

Mr. Dean had drafted for Intermedics' policy with Travelers. (*Id.* at 558:11-19, 560:13-561:1.)

After Mr. Dean became SulzerMedica's insurance broker SulzerMedica had a recall on a pacemaker. (*Id.* at 557:20-558:10.) This recall prompted George Keller, President of XLIA, to discuss the batch coverage in the SulzerMedica policy with Mr. Dean. (*Id.* at 561:2-17.) In the course of these conversations Mr. Dean explained the batch coverage to Mr. Keller and they eventually reached a common understanding. (*Id.* at 561:18-22.) The common understanding they reached was consistent with the previously described explanation Mr. Dean provided during his conference calls with Stryker. (*Id.* at 562:13-563:6.) SulzerMedica had two subsequent recalls and the batch coverage was applied consistent with Mr. Dean's understanding of the batch coverage. (*Id.*)

Returning to the conference calls between Mr. Dean and Stryker in December of 1999, the Court is cognizant that at the time Mr. Dean was not an employee of XLIA. Mr. Dean's employment does not, however, diminish the significance of the explanations that he provided to Stryker. XLIA's underwriter, Mr. Kuchinic, wrote a handwritten note to Geoff Welsher, on December 10, 1999, regarding a conference call between Mr. Dean and Stryker and stated that: "Danny sold the deal to Stryker atty." (Trial Ex. 63; Kuchinic Dep. 188:1-8.) Mr. Kuchinic similarly acknowledged the role of Mr. Dean in an email to other XLIA employees on December 28, 1999. (Trial Ex. 34; Kuchinic Dep. 91:6-17, 95:11-96:1, 96:10-24.) XLIA was aware of Mr. Dean's conversations with Stryker and that in those conversations he had provided an explanation of the Medical Products Endorsement.

(Kuchinic Dep. 95:11-96:24.) Additionally, XLIA knew the substance of Mr. Dean's understanding of the Medical Products Endorsement because of the conversations between Mr. Dean and Mr. Keller.

At the time the parties entered into the Policy both parties had the same understanding of the Medical Products Endorsement. Both parties had come to understand the Medical Products Endorsement from explanations provided by Mr. Dean. The shared intent of the parties is consistent with the Court's analysis of the text of the Medical Products Endorsement. Therefore, the Court finds that Stryker and XLIA intended that the Commercial Umbrella Policy, as modified by the Medical Products Endorsement, would cover all claims and lawsuits involving products in a single batch, if bodily injury took place after January 1, 2000.

B. Did the following individuals suffer some bodily injury from a defective Uni-Knee between January 1, 2000, and January 1, 2001?⁵

The special verdict form asks whether seventy-seven claimants suffered bodily injury during the policy period. The parties have stipulated that sixty-six of the claimants did suffer bodily injury during the policy period. (Aug. 21, 2006 Order Granting Stipulation, Docket #829; Jan. 4, 2007 Order Granting Stipulation, Docket #841.) The Court therefore finds that

⁵The Court's finding as to the first question makes resolution of this second question unnecessary. The Court will, however, resolve this question as the Court previously determined that the trier of fact should answer questions consistent with the parties' alternative interpretations of when bodily injury had to take place.

the sixty-six claimants identified in the stipulations suffered bodily injury between January 1, 2000, and January 1, 2001.⁶

The Court next addresses the eleven claimants for whom there was no stipulation. The eleven claimants at issue are: Nancy Burkhard, Leslie Carr, Carol Johansen, Barbara Kingdom, Roy Martin, Stella Matalas, Delbert Napier, Shirley Olsen, Evelyn Rogers, Norman Rosen and Sharon Shultz. The only witness with respect to when these eleven claimants suffered bodily injury was Thomas P. Schmalzried, M.D. Dr. Schmalzried testified live at trial as an expert witness on behalf of Plaintiffs. XLIA stipulated to Dr. Schmalzried's expertise. (Trial Tr. 349:7-22.) The Court found Dr. Schmalzried to be a well-qualified and credible witness.

As to Nancy Burkhard, Dr. Schmalzried testified that there was nothing in Ms. Burkhard's medical records indicating that she experienced bodily injury during the policy period. (Schmalzried Test., Trial Test. 404:3-8, 418:18-419:1.) Dr. Schmalzried also

⁶The sixty-six claimants identified by the stipulations are: Dorothea Alexander, Nancy Bartlett, Arnold Braswell, Debbie Brickman, Sam Bridgers, Elaine Brincefield, Mary Burns, Norman Chaney, Barbara Cox, James Crouch, Chauncey Custer, Delores Doeding, James Eccles, Wilma Ednie, Richard Fields, Winifred Fisher, Leonard Forman, Marguerite Fry, Paul Gaffney, Fred Galzerano, Oscar Garcia, Lawrence Glahe, Rita Griggs, Doris Horn, Freda Inlow, Eileen Johnson, Linda Kamen, Nirmal Khanna, Donald King, Diane Kitchens, Dorothy Kuethe, Christa Kulbe, James Laird, Suzanne Ledbetter, David Lell, George Lewett, Ann Lueders, Ruth MacEwen, Donald Major, Theda Massie, Betsy McKelvain, Norman Melancon, Michael Moffat, Pam Murray, Peter Nelson, Carmen O'Leary, Dora Orr, David Orrik, Saul Penn, Donald Priest, Francis Reidy, Richard Schulze, Ira Seiler, Delbert Sheffler, John Soho, Gerald Spreen, Hugo Thornton, Joan Thorsness, Virginia Tilford, Joel Tuitt, Barbara Ward, William Ways, Althea Wenzel, Margaret Wilks, Donna Zalusky-Nova and Patricia Zoeckler.

testified that on March 19, 2002, Ms. Burkhard's medical records indicate that she had a "good result" from the Uni-Knee implant. (*Id.* at 403:22-404:2.) The Court finds that Nancy Burkhard did not suffer bodily injury between January 1, 2000, and January 1, 2001.

As to Leslie Carr, Dr. Schmalzried testified that an arthroscopy was done on Ms. Carr on August 21, 2002. (*Id.* at 407:6-13.) In the course of the arthroscopy loose polyethylene particles were removed. (*Id.* at 407:14-22.) Dr. Schmalzried testified that the removal of polyethylene particles was consistent with wear due to oxidation. (*Id.* at 407:23-408:8.) Dr. Schmalzried testified that in his opinion it was "more likely than not" that there was bodily injury in the year 2000. (*Id.* at 408:9-13.) Dr. Schmalzried also testified that "there isn't good medical documentation in the calendar year" (*Id.* at 408:16:19.) The Court finds Dr. Schmalzried's more specific statements, which support the conclusion that there was not bodily injury in the policy year, more persuasive than his generalized "more likely than not" statement. The Court also notes that as to eight of the claimants Dr. Schmalzried described his conclusion as to injury in the policy year as being "[t]o a reasonable degree of medical certainty," but did not so indicate as to Ms. Carr. (*Id.* at 379:6-8, 384:1-3, 386:17-20, 390:25-391:2, 394:6-8, 396:7-10, 398:14-16, 401:13-15.) The Court finds that Leslie Carr did not suffer bodily injury between January 1, 2000, and January 1, 2001.

As to Carol Johansen, Dr. Schmalzried testified that Ms. Johansen's medical records indicated that in the policy year x-rays showed a gap between her tibia and the UHMWPE

component of her Uni-Knee. (*Id.* at 380:21-381:13.) Dr. Schmalzried attributed the gap to bone loss caused by the implantation of an expired Uni-Knee. (*Id.* at 381:14-22.) Based on this, Dr. Schmalzried testified that "[t]o a reasonable degree of medical certainty" Ms. Johansen suffered bodily injury in the policy year. (*Id.* at 378:23-379:13.) The Court finds that Carol Johansen suffered bodily injury between January 1, 2000, and January 1, 2001.

As to Barbara Kingdom, Dr. Schmalzried testified that Ms. Kingdom's medical records indicated that the UHMWPE component of her Uni-Knee had decreased in thickness by April 18, 2000. (*Id.* at 387:1-18, 388:15-19.) Dr. Schmalzried also testified that a total knee arthroplasty was performed on February 21, 2001, which would have required that the symptoms warranting the total knee arthroplasty manifested prior to January 1, 2001. (*Id.* at 389:5-390:20.) Based on this, Dr. Schmalzried testified that "[t]o a reasonable degree of medical certainty" Ms. Kingdom suffered bodily injury in the policy year. (*Id.* at 386:13-20.) The Court finds that Barbara Kingdom suffered bodily injury between January 1, 2000, and January 1, 2001.

As to Roy Martin, Dr. Schmalzried testified that Mr. Martin's medical records indicated that he experienced symptoms of inflammation in December of 2000. (*Id.* at 384:11-385:7.) Dr. Schmalzried testified that the symptoms Mr. Martin experienced in 2000, in conjunction with the wear on the UHMWPE component discovered when the knee was revised in 2002, indicate that the inflammation experienced in December of 2000 was

attributable to the Uni-Knee. (*Id.* at 385:8-386:12.) Based on this, Dr. Schmalzried testified that "[t]o a reasonable degree of medical certainty" Mr. Martin suffered bodily injury in the policy year. (*Id.* at 383:23-384:3.) The Court finds that Roy Martin suffered bodily injury between January 1, 2000, and January 1, 2001.

As to Stella Matalas, Dr. Schmalzried testified that Ms. Matalas' medical records indicated that she had Uni-Knees implanted in both knees. In 2000, x-rays of her left knee showed accelerated wear of the tibial component of her Uni-Knee. (*Id.* at 392:3-15.) Dr. Schmalzried testified that the post-operative report for Ms. Matalas' revision surgery confirmed that the UHMWPE component of the Uni-Knee implanted in her left knee had failed. (*Id.* at 392:21-394:2.) Based on this, Dr. Schmalzried testified that "[t]o a reasonable degree of medical certainty" Ms. Matalas suffered bodily injury in the policy year. (*Id.* at 390:21-391:2.) The Court finds that Stella Matalas suffered bodily injury between January 1, 2000, and January 1, 2001.

As to Delbert Napier, Dr. Schmalzried testified that "[t]here is little medical documentation on this patient in the year 2000." (*Id.* at 404:11-12.) Dr. Schmalzried did not otherwise testify as to a basis for concluding that Mr. Napier suffered bodily injury in the year 2000. The Court finds that Delbert Napier did not suffer bodily injury between January 1, 2000, and January 1, 2001.

As to Shirley Olsen, Dr. Schmalzried testified that Ms. Olsen's medical records indicated that a revision surgery on April 22, 2002, revealed that the UHMWPE component

of her Uni-Knee had completely failed. (*Id.* at 401:17-402:3.) Dr. Schmalzried testified that the complete failure of the UHMWPE component indicated that the component had begun to fail within weeks of the Uni-Knee being implanted in the year 2000. (*Id.* at 402:12-403:21.) Based on this, Dr. Schmalzried testified that "[t]o a reasonable degree of medical certainty" Ms. Olsen suffered bodily injury in the policy year. (*Id.* at 401:8-15.) The Court finds that Shirley Olsen suffered bodily injury between January 1, 2000, and January 1, 2001.

As to Evelyn Rogers, Dr. Schmalzried testified that Ms. Rogers' medical records indicated that during an office visit in early 2001 she demonstrated clinical symptoms of inflammation in her knee and she described experiencing symptoms of inflammation in the year 2000. (*Id.* at 394:10-396:2.) Based on this, Dr. Schmalzried testified that "[t]o a reasonable degree of medical certainty" Ms. Rogers suffered bodily injury in the policy year. (*Id.* at 394:3-9.) The Court finds that Evelyn Rogers suffered bodily injury between January 1, 2000, and January 1, 2001.

As to Norman Rosen, Dr. Schmalzried testified that Mr. Rosen's medical records indicated that x-rays taken on August 1, 2000, showed a "very high amount" of wear of the UHMWPE component of his Uni-Knee in a short period of time. (*Id.* at 397:12-25.) Dr. Schmalzried also testified that Mr. Rosen's medical records indicated swelling and activity-related symptoms in the year 2000. (*Id.* at 398:6-9.) Based on this, Dr. Schmalzried testified that "[t]o a reasonable degree of medical certainty" Mr. Rosen suffered bodily injury

in the policy year. (*Id.* at 396:3-10.) The Court finds that Norman Rosen suffered bodily injury between January 1, 2000, and January 1, 2001.

As to Sharon Shultz, Dr. Schmalzried testified that Ms. Shultz's medical records showed persistent deterioration of the UHMWPE component of her Uni-Knee and that she experienced activity-related symptoms in the year 2000. (*Id.* at 400:11-21.) Based on this, Dr. Schmalzried testified that "[t]o a reasonable degree of medical certainty" Ms. Schultz suffered bodily injury in the policy year. (*Id.* at 398:10-17.) The Court finds that Sharon Shultz suffered bodily injury between January 1, 2000, and January 1, 2001.

III.

Under Michigan law, the insurer bears the burden of proof on exclusions from coverage. (Oct. 14, 2005 R&R, at 5, *approved and adopted by* July 14, 2006 Order, Docket #814.); *Morrill v. Gallagher*, 370 Mich. 578, 587, 122 N.W.2d 687 (1963). Questions 3 and 4 on the special verdict form relate to exclusions from coverage. Therefore, Defendant has the burden of proof on Questions 3 and 4. The Court must determine the facts under a preponderance of the evidence standard. *Milliken*, 422 Mich. at 89.

A. **Who is it that must know or suspect the defect or deficiency in the Uni-Knees before January 1, 2000, in order for coverage to be excluded?**

The third paragraph of the Medical Products Endorsement provides that: "Batch coverage shall not apply to any loss, which arises out of a defect, [*sic*] or deficiency that is known or suspected prior to 1-1-00." (Policy, Endorsement No. 17.) The Court previously determined that the Medical Products Endorsement is ambiguous as to whose knowledge or

suspicion is relevant. (Aug. 17, 2005 Op. 21-22; July 14, 2006 Op. 16.) The meaning of an ambiguous provision of a contract is a question of fact to be decided by the trier of fact. *See Klapp*, 468 Mich. at 469. Plaintiffs contend that the parties intended to exclude coverage if an officer or a risk manager knew of or suspected the defect or deficiency. XLIA contends that the parties intended to exclude coverage if any employee knew of or suspected the defect or deficiency.

The "known or suspected" provision does not contain any language identifying who must know of or suspect the defect or deficiency. In contrast, the next sentence indicates that only "an officer of Stryker" can send an "advisory memorandum" which establishes a batch. (Policy, Endorsement No. 15.) The decision to include language in the next sentence limiting that provision to officers of Stryker suggests that the "known or suspected" provision was to apply to any employee. The "officer of Stryker" language demonstrates that the parties knew how to limit provisions to certain employees. Contrasting these two sentences does not resolve the ambiguity, thus the Court must consider extrinsic evidence about the Medical Products Endorsement.

Mr. Cartier, an attorney employed by Stryker, was charged with assisting Stryker's risk management team evaluate XLIA's proposed policy. (Hall Test. 484:11-18.) As originally proposed by XLIA, any employee of Stryker could have sent an "advisory memorandum" that established a batch under the Medical Products Endorsement. (Cartier Test. 312:4-313:6.) Stryker was concerned about the possibility of any employee being able

to trigger a batch, so Stryker proposed an amendment to paragraph four of the Medical Products Endorsement. (*Id.* at 312:15-313:1.) XLIA agreed to Stryker's proposed amendment to paragraph four, so only an officer of Stryker could trigger a batch. (*Id.* at 313:2-6.)

Stryker did not propose any amendments to the "known or suspected" provision of the Medical Products Endorsement. (Puscas Dep. 219:14-22.) Though Stryker did unsuccessfully attempt to negotiate changes to paragraphs one, two and three of the Medical Products Endorsement. (Cartier Test. 312:10-14.) Thus, the parties understood that in the absence of language identifying a particular type or level of employee, policy language was understood to refer to all employees; however, neither party proposed limiting the employees to which the "known or suspected" provision would apply.

Stryker contends that the testimony of Mr. Dean indicates that the parties understood that the "known or suspected" provision was limited to officers and risk managers. Mr. Dean testified that in his conversations with Mr. Keller, they reached an understanding about the "known or suspected" provision in the SulzerMedica policy. (Dean Test. 566:9-567:25.) Mr. Dean and Mr. Keller came to understand the "known or suspected" provision in the SulzerMedica policy to only apply to officers or risk managers. (*Id.* at 567:12-25.) Mr. Dean testified that in his conversations with Stryker he never discussed the "known or suspected" provision. (*Id.* at 587:18-588:3.) Plaintiffs did not provide any evidence that Mr. Keller's conversations with Mr. Dean about the "known or suspected" provision informed the parties

intent with respect to the policy purchased by Stryker. In contrast, the Court's earlier reliance on Mr. Dean's understanding about bodily injury in the policy period was premised on Mr. Dean's understanding having been conveyed to both parties. As Mr. Dean did not relay to Stryker this aspect of his earlier conversations with Mr. Keller, Stryker could not have intended to enter into the Policy based on the understanding reached between Mr. Dean and Mr. Keller. Therefore, the Court finds the negotiations as to other parts of the Medical Products Endorsement, particularly paragraph four, more persuasive than Mr. Dean's testimony on this issue.

Stryker also argues that the "known or suspected" provision must be construed in its favor because exclusions from coverage, when ambiguous, are strictly construed against the insurer. (July 14, 2006 Op. 16-17.) The rule that exclusions from coverage are strictly construed against the insurer is inapplicable if the exclusion is unambiguous after extrinsic evidence has been considered. (*Id.* at 17.) The "known or suspected" provision is ambiguous when only the text of the Medical Products Endorsement is considered. The provision is, however, unambiguous when evaluated in the context of the drafting history of the Medical Products Endorsement. Therefore, the rule that exclusions from coverage are strictly construed against the insurer is inapplicable to the "known or suspected" provision.

The intent of the parties was that Policy language not identifying particular types or levels of employees would apply to all employees. The "known or suspected" provision of the Medical Products Endorsement does not identify any particular type or level of employee.

Thus, the intent of the parties was for the "known or suspected" provision of the Medical Products Endorsement to apply to any employee. The Court finds that under paragraph three of the Medical Products Endorsement, if any employee knew of or suspected the defect or deficiency in the Uni-Knees prior to January 1, 2000, then there is no batch coverage for the Uni-Knees.

B. Did any employee of Plaintiffs know of or suspect the defect or deficiency in the Uni-Knees prior to January 1, 2000?

The Court must next determine whether any employee of Stryker or HOC knew of or suspected the defect or deficiency in the Uni-Knees prior to January 1, 2000. The Court previously determined that "the Duracon Uni-Knees were defective if they were available in inventory for implantation by physicians beyond their shelf life, that is beyond five years." (July 14, 2006 Op. 13.) The specific question is whether prior to January 1, 2000, any employee of Stryker or HOC knew or suspected that Uni-Knees were available in inventory for implantation by physicians beyond their shelf life.

Edward B. Lipes, Group President of HOC, testified live at trial. The Court found Mr. Lipes to be forthright and a credible witness. Elizabeth A. Staub, Vice-President of Regulatory, Quality and Clinical at HOC, also testified live at trial. The Court found Ms. Staub to be forthright and a credible witness. The Court finds the chronology of events to be as follows.

After the acquisition of Howmedica Inc. through 2001, the overriding concern at HOC was the integration of the two companies. (Lipes Test. 101:15-103:19.) The integration of

the two companies was challenging because of the size of Howmedica Inc. (Staub Test., Trial Tr. 173:3-174:14.) Howmedica Inc. and its parent company Pfizer, represented to Stryker and Osteonics Corporation that all products containing polyethylene had been entered into the poly-filter file.⁷ (Lipes Test. 94:23-95:12.) Howmedica Inc. and Pfizer also represented that the poly-filter file had a perfect track record. (*Id.* at 91:23-92:24, 95:9-12.) Consistent with these representations, the purchase agreement specifically indicated that all inventory transferred from Howmedica Inc. would be fit for sale. (*Id.* at 95:13-21.) The amount of inventory of the newly formed company made it impractical for HOC to physically review its entire inventory. (*Id.* at 89:13-90:16; Staub Test. 269:2-12.)

⁷XLIA submitted the deposition of Dyanne Diemer Kashuba and a memorandum she wrote on October 28, 1997. The October 28, 1997, memorandum states in relevant part that:

Because of the many problems we have experienced in the past with this product line, I thought it would be a good idea to get a jump start on the reordering of this inventory. Because of the poly dating policy, **all** of the inserts will be outdated **May 1998**. So that we are not caught without any product to supply the field, we should look into the following issues

(Trial Ex. Q (emphasis in original).) The Court notes that this memorandum was written prior to Stryker's acquisition of Howmedica Inc. Additionally, Stryker did not receive a copy of this memorandum until it was produced by Pfizer during discovery in one of the underlying cases. (Trial Ex. 220, at ¶ 3.) Even assuming any employees of HOC had knowledge of this memorandum, the memorandum indicates that after May of 1998 the UHMWPE component of the Uni-Knees will not be available. The memorandum is premised on the effectiveness of the poly-filter file preventing the distribution of expired Uni-Knees. (Kashuba Dep, in *Bartlett v. Stryker Corp.*, 30:7-31:9.) Thus, the memorandum does not provide a basis for concluding that any employees knew of or suspected the defect prior to January 1, 2000.

Mr. Lipes selected Ms. Staub to be the quality assurance person responsible for the newly formed company. (Lipes Test. 100:6-11; Staub Test. 172:19-173:2.) Mr. Lipes selected Ms. Staub because "she was tough enough and smart enough and, you know, had the right sense of values to lead that organization" (Lipes Test. 100:12-18.) Both Mr. Lipes and Ms. Staub were committed to maintaining a very high standard of quality. (Staub Test. 181:18-182:7.) HOC's commitment to quality was based in part on HOC's reputation for quality being critical to the continued success of the company. (*Id.* at 180:7-181:4, 181:20-182:7.)

Howmedica Inc. had a system referred to as the Product Experience Report ("PER") for addressing quality complaints. (*Id.* at 179:8-21.) The PER system was based on a network database connecting all of the manufacturing facilities and it was more sophisticated than Osteonics Corporation's system. (*Id.* at 179:14-180:2.) Ms. Staub decided to adopt Howmedica Inc.'s PER system for HOC. (*Id.* at 180:2-4.)

Under the PER system, the first step was the filing of a complaint, which was typically done by a sale representative. (*Id.* at 182:8-183:11.) Each report is then referred to as a PER. (*Id.* at 189:6-9.) An employee in the quality assurance department at HOC would then create a file for the complaint and gather as much information as possible about the complaint (e.g., medical records, lot codes). (*Id.* at 182:8-183:11.) Once the file was complete, an investigator at the facility where the product was manufactured would undertake an

investigation. (*Id.* at 183:8-184:15.) In 1999, HOC received approximately 150 PERs per month. (*Id.* at 187:23-188:3.)

Separate from the investigation of individual PERs, on a quarterly basis HOC would review the PER system for trends. (*Id.* at 186:17-22.) In the summer of 1999, Wayne Irwin, Manager of the Product Surveillance Department at HOC, advised Ms. Staub the he had seen a few complaints in which polyethylene older than five years had been implanted. (*Id.* at 225:12-226:9.) Mr. Irwin also advised Ms. Staub that it had been five years since Howmedica Inc. had last advised hospitals and doctors of the five-year shelf life policy and recommended that she send out a reminder about the five-year policy. (*Id.* at 226:5-9.)

Mr. Irwin told Ms. Staub that he did not think there was a trend. (*Id.* at 225:25-226:8.) Instead, Mr. Irwin advised Ms. Staub that he believed that the instances of expired polyethylene he had observed were a hospital based problem. (*Id.* at 225:25-226:8.) Ms. Staub agreed with Mr. Irwin and so on December 30, 1999, Ms. Staub sent a memorandum to all "Stryker Howmedica Osteonics distribution and sales units, and independent distributors" (the "Staub Memo"). (Trial Ex. 21.) The Staub Memo reiterated the five-year shelf life policy and the procedures in place to ensure compliance with the policy.

In deciding to send the Staub Memo, Ms. Staub never thought that the instances of expired polyethylene that prompted Mr. Irwin's suggestion could have been the result of HOC shipping expired polyethylene. (Staub Test. 227:17-229:12.) At the time Ms. Staub

sent the memo she had not reviewed the PERs underlying Mr. Irwin's suggestion. (*Id.* at 227:17-228:2.) She also did not know what types of products were involved in the PERs identified by Mr. Irwin. (*Id.* at 232:24-233:9.)

In the Spring of 2000, after it was evident that there was an issue with the Uni-Knees, a lawyer working with Stryker asked Ms. Staub to identify the PERs that had prompted Mr. Irwin to recommend sending a reminder about the five-year policy. (*Id.* at 238:11-239:13.) Ms. Staub asked a member of her staff to search the PER system to identify the individual PERs that had prompted Mr. Irwin. (*Id.* at 239:14-240:1.) That search identified three individual PERs. (*Id.* at 240:1; Trial Ex. 24.) Of the three identified PERs, only one involved a Uni-Knee. (Staub Test. 243:3-8; Trial Ex. 24.) Neither of the other two products were determined to have gotten through the poly-filter file. (Staub Test. 254:13-16, 255:2-258:12.)

The PER that involved a Uni-Knee was the PER for Terry Hipps. (Staub Test. 243:3-17; Trial Ex. Y2.) The Hipps complaint was submitted by a HOC service representative in Florida on November 2, 1999.⁸ (Trial Ex. Y2.) The device had been manufactured in Limerick, Ireland. Therefore the investigation, which was opened on March 28, 2000, was

⁸Jadwiga Degrado, a quality assurance representative at HOC, entered the Hipps complaint into the PER system. (Degrado Dep. 74:25-75:3, 159:20-160:16; Trial Ex. 22.) XLIA contends that based on having entered the Hipps complaint Ms. Degrado knew of the defect in the Uni-Knees. Ms. Degrado having entered the Hipps complaint does not provide a basis for inferring that she knew of the defect in the Uni-Knees. There is nothing in Ms. Degrado's deposition which indicates that she even suspected the defect in the Uni-Knees based on having entered the Hipps complaint.

done in Limerick, Ireland. (Trial Ex. 23.) Prior to January 1, 2000, the Hipps PER was the only PER for the United States that indicated that a Uni-Knee had been implanted beyond the five-year shelf life. A single PER cannot suggest a trend. Though the Hipps complaint was filed before January 1, 2000, the investigation into the Hipps PER was not opened until almost three months after January 1, 2000. Therefore no one evaluated the Hipps PER in a manner that could have recognized the defect prior to January 1, 2000. The facts of the Hipps PER do not provide a basis for inferring that any employee knew of or suspected the defect before January 1, 2000. XLIA contends that the Staub Memo indicates that an employee knew of or suspected the defect in the Uni-Knee prior to January 1, 2000. The events leading up to the issuance of the Staub Memo make clear that the Staub Memo was not predicated on a suspicion, much less knowledge, about the defect in the Uni-Knees.

The steps HOC took after the discovery of the defect strongly counsel against inferring that any employee of Stryker or HOC knew of or suspected the defect in the Uni-Knees prior to January 1, 2000. In February of 2000, Dr. J. Kent Pike, a well-respected orthopedic surgeon in Coeur D'Alene, Idaho, contacted Jerry Traynham, a sales representative at HOC. (Pike Dep. 6:14-7:14, 37:9-38:7, 51:25-52:6.) Dr. Pike contacted Mr. Traynham because he had observed delaminating polyethylene in two, possibly three, then recent arthroscopies of patients who had Uni-Knees. (Pike Dep. 32:25-38:04.) Sometime in the spring of 2000, Mr. Traynham then contacted Bradley Chase, who was the

product manager for Uni-Knees.⁹ (Trial Ex. 221; Chase Dep. 31:19-21, 224:6-16.) Dr. Duane Anderson, another well-respected orthopedic surgeon in Coeur D'Alene, Idaho, had experiences similar to those of Dr. Pike.

In April of 2000, Dr. Gerard A. Engh, a well-respected orthopedic surgeon in Mt. Vernon, Virginia, contacted Jack Reagan, a sales representative with HOC. (Engh Dep. 10:21-11:3, 23:23-26:5.) Dr. Engh contacted Mr. Reagan because in April of 2000 he did a revision surgery on a patient with a Uni-Knee implanted less than two years earlier and the polyethylene component was fragmented. (Engh Dep. 24:11-25:24.) Dr. Engh also had a number of other patients who were experiencing inflammation and other problems associated with their Uni-Knee implants. (Engh Dep. 22:9-23:22.)

Upon learning of Dr. Pike's experiences, Ms. Staub immediately began an investigation. (Staub Test. 216:25-219:5.) Then in April of 2000, the situation was brought to the attention of Mr. Lipes. (Lipes Test. 104:11-105:11.) In response, Mr. Lipes

⁹After receiving the call from Mr. Traynham, Mr. Chase went to HOC's warehouse in Mahwah, New Jersey. While at the Mahwah warehouse, Mr. Chase visually inspected the Uni-Knees in inventory and removed those that were expired. (Chase Dep. 90:8-91:2, 92:1-93:21, 98:17-99:5, 99:8-21, 100:19-101:14, 104:5-107:9.) Though Mr. Chase indicated that this took place in 1999, he also acknowledged that all of this occurred after he received the call from Mr. Traynham. (Chase Dep. 224:3-225:12.) The testimony of Dr. Pike and the affidavit of Mr. Traynham both clearly indicate that Mr. Traynham's call to Mr. Chase could not have occurred before February of 2000. (Trial Ex. 221, at ¶¶ 8-10; Pike Dep. 35:1-38:17.) Mr. Chase also testified that the warehouse he visited was managed by Michael Gaines. (Chase Dep. 99:13-15, 17.) Mr. Gaines, National Loaner Bank Team Leader at HOC, testified live at trial and the Court found him to be a credible witness. Mr. Gaines specifically recalled the call from Mr. Chase and testified that the call did not take place until the first quarter of 2000. (Gaines Test., Trial Tr. 621:6-623:24.)

committed the full attention of senior management and assembled a task force to investigate the situation. (Lipes Test. 105:3-11, 106:8-18, 108:1-5.) Mr. Lipes also sent a letter to Dr. Pike and asked for a meeting with him. (*Id.* at 106:19-23.) In late April or May of 2000, the task force determined that the Uni-Knees had been omitted from the poly-filter file, which had resulted in HOC shipping expired Uni-Knees. (*Id.* at 106:24-107:15.) Upon learning that the failure of the implants was due to a failure by HOC, Mr. Lipes believed that it was very important for him to meet with Dr. Pike to explain that HOC was going to take responsibility for the problem and that HOC was going to work with doctors to fix the situation. (*Id.* at 107:7-15, 110:2-11; Trial Ex. 14.)

Mr. Lipes did eventually have a meeting with Dr. Pike. (Lipes Test. 111:20-113:13.) Based on a request from Dr. Pike at the meeting between he and Mr. Lipes, HOC began providing a letter for surgeons to give to their patients. (Lipes Test. 114:4-17; Trial Exs. 16, N.) In the letter HOC acknowledged that it was responsible for the situation and that it was taking responsibility for correcting the situation. (Lipes Test. 114:4-17; Trial Exs. 16, N.) Upon learning that Dr. Engh was experiencing problems with Uni-Knees similar to those of Dr. Pike, Mr. Lipes met with Dr. Engh. (Lipes Test. 116:25-118:23.)

After the task force determined that expired Uni-Knees were available in inventory, HOC immediately placed a hold on all Uni-Knees and then pulled all Uni-Knees out of inventory, including those in inventory at hospitals. (Gaines Test. 624:22-625:4; Lipes Test. 118:24-119:11.) This occurred in late April or May of 2000. (Lipes Test. 119:9-11.) HOC

then took steps to identify the doctors who might have implanted a Uni-Knee. (Lipes Test. 119:12-120:1.) HOC then sent a letter, similar to the letter sent to Dr. Pike, to every doctor who had implanted a Uni-Knee. (Lipes Test. 119:12-121:1; Trial Ex. 15.)

Ms. Staub testified that upon learning that the Uni-Knees had been omitted from the poly-filter file:

everybody kind of got that kind of sick feeling in their stomach. I mean, it's not to say we're perfect and we never make mistakes, because we do. But we had never seen a failure on our part result in such a large number of patients who had to have another series of surgery [*sic*], you know, the pain and hardship of trying to decided whether or not they wanted to be operated on again. You know, everybody knows somebody who's gone through these medical procedures and it's a great physical and emotional strain, and we caused it. It was not a good time.

(Staub Test. 223:16-25 (emphasis added).) The Court found this portion of Ms. Staub's testimony very persuasive as to HOC not knowing or suspecting the defect prior to January 1, 2000. The recognition of the significance of the failure of the poly-filter file expressed by Ms. Staub extended throughout the HOC workforce. (Gaines Test. 624:12-15.)

Mr. Cartier, Mr. Hall, Mr. Lipes and Ms. Staub, all testified that they did not know of or suspect the defect in the Uni-Knees prior to January 1, 2000. (Cartier Test. 313:22-314:5; Hall Test. 509:25-510:5; Lipes Test. 131:13-132:4, 132:14-18; Staub Test. 222:18-22.) Moreover, each of these individuals, but particularly Mr. Lipes and Ms. Staub, made clear that if they had known of or suspected the defect before April of 2000, their response would have been the same as it was in April of 2000. (Hall Test. 507:7-14; Lipes Test. 131:13-132:4; Staub Test. 222:23-223:12.) This testimony is consistent with the strong

interest of Stryker and HOC in maintaining a reputation for quality products. (Hall Test. 491:21-492:15; Lipes Test. 62:13-65:3, 132:19-22.)

XLIA contends that the consistency between the testimony of Mr. Cartier, Mr. Hall, Mr. Lipes and Ms. Staub, is the result of collusion among them to cover-up the fact that they knew of the defect in the Uni-Knee prior to January 1, 2000. First, the Court found all four of these witness to be credible, honest and forthright. Second, though in some instances consistency among witnesses indicates collusion, consistency among witnesses is far more likely to be indicative of the truth. There was *nothing* in the testimony of these four witnesses which suggests that they were repeating agreed upon testimony or in any other way colluding. As the Court earlier indicated, the Court found these witnesses to be credible and honest.

The Court has found that prior to January 1, 2000, no employee of Stryker or HOC knew that Uni-Knees were available in inventory for implantation by physicians beyond their shelf life. The Court must also consider whether prior to January 1, 2000, any employee of Stryker or HOC suspected that Uni-Knees were available in inventory for implantation by physicians beyond their shelf life. The employees of HOC, and before that Howmedica Inc., had placed complete confidence in the poly-filter file. (Kashuba Dep, in *Bartlett v. Stryker Corp.*, 30:7-31:9; Lipes Test. 91:10-24, 94:23-95:12; O'Connor Test. 453:17-23; Staub Test. 318:20-23.) As a result of that confidence, events involving expired polyethylene were attributed to hospitals not properly rotating their inventory and other similar causes, without

raising the specter of a failure in HOC's distribution system. (Staub Test. 210:2-20, 212:20-213:6.) Though the confidence in the poly-filter file was misplaced, that error in judgment in no way indicates that any employee suspected the defect prior January 1, 2000. Even if absent that confidence, some employees might have had suspicions prior to January 1, 2000, that is simply not the environment in which HOC employees were operating. Lastly, in early 2000 when it became apparent that there was an issue with the Uni-Knees, an investigation was initiated. This suggests that had there been suspicions prior to January 1, 2000, an investigation would have been launched when those suspicions arose. (Hall Test. 507:7-14; Lipes Test. 131:20-132:4; Staub Test. 222:23-223:12.)

The Court finds that prior to January 1, 2000, no employee of Stryker or HOC knew or suspected that Uni-Knees were available in inventory for implantation by physicians beyond their shelf life.

IV.

For the reasons explained in this opinion, the Court finds the following facts:

1. Stryker Corporation and XL Insurance America Inc. intended that the Commercial Umbrella Policy, as modified by the Medical Products Endorsement, would cover all claims and lawsuits involving products in a single batch, if bodily injury took place after January 1, 2000.
2. The following individuals suffered bodily injury from a defective Duracon Uni-Knee between January 1, 2000, and January 1, 2001: Dorothea Alexander, Nancy Bartlett,

Arnold Braswell, Debbie Brickman, Sam Bridgers, Elaine Brincefield, Mary Burns, Norman Chaney, Barbara Cox, James Crouch, Chauncey Custer, Delores Doeding, James Eccles, Wilma Ednie, Richard Fields, Winifred Fisher, Leonard Forman, Marguerite Fry, Paul Gaffney, Fred Galzerano, Oscar Garcia, Lawrence Glahe, Rita Griggs, Doris Horn, Freda Inlow, Carol Johansen, Eileen Johnson, Linda Kamen, Nirmal Khanna, Donald King, Barbara Kingdom, Diane Kitchens, Dorothy Kuethe, Christa Kulbe, James Laird, Suzanne Ledbetter, David Lell, George Lewett, Ann Lueders, Ruth MacEwen, Donald Major, Roy Martin, Theda Massie, Stella Matalas, Betsy McKelvain, Norman Melancon, Michael Moffat, Pam Murray, Peter Nelson, Carmen O'Leary, Shirley Olsen, Dora Orr, David Orrik, Saul Penn, Donald Priest, Francis Reidy, Evelyn Rogers, Norman Rosen, Richard Schulze, Ira Seiler, Delbert Sheffler, Sharon Shultz, John Soho, Gerald Spreen, Hugo Thornton, Joan Thorsness, Virginia Tilford, Joel Tuitt, Barbara Ward, William Ways, Althea Wenzel, Margaret Wilks, Donna Zalusky-Nova and Patricia Zoeckler.

3. The following individuals did not suffer bodily injury from a defective Duracon Uni-Knee between January 1, 2000, and January 1, 2001: Nancy Burkhard, Leslie Carr and Delbert Napier.
4. Stryker Corporation and XL Insurance America Inc. intended that the last sentence of paragraph three of the Medical Products Endorsement would apply to any employee of Stryker Corporation or Howmedica Osteonics Corporation.

5. Prior to January 1, 2000, no employee of Stryker Corporation knew or suspected that Duracon Uni-Knees were available in inventory for implantation by physicians beyond their shelf life.
6. Prior to January 1, 2000, no employee of Howmedica Osteonics Corporation knew or suspected that Duracon Uni-Knees were available in inventory for implantation by physicians beyond their shelf life.

V.

Plaintiffs have established the *prima facie* elements for coverage under the Policy by a preponderance of the evidence. *See supra* Part II. XLIA has not established that any of the exclusions in the Policy are applicable to Plaintiffs. *See supra* Part III. Therefore the Court makes the following conclusions of law:

1. Stryker Corporation is entitled to batch coverage under the Commercial Umbrella Policy for the batch of defective Duracon Uni-Knees defined by the July 28, 2000, advisory memorandum.
2. XL Insurance America Inc. had and continues to have a duty to defend and a duty to indemnify Stryker Corporation for the batch of defective Duracon Uni-Knees defined by the July 28, 2000, advisory memorandum.

Based on the Court's bifurcation of this case, the reasonableness of the amount paid by Plaintiffs in resolving the underlying claims, and other questions as to the amount of

damages, are reserved for the second phase of the trial. A partial judgment will be entered consistent with this opinion.

Date: April 3, 2007

/s/ Robert Holmes Bell

ROBERT HOLMES BELL

CHIEF UNITED STATES DISTRICT JUDGE